

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Wen-Tsan Chang et al.
Serial No. : 10/727,355
Filed : December 3, 2003
Title : ANTIVIRUS RNA

Art Unit : 1635
Examiner : Dana H. Shin
Conf. No. : 5446

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF WEN-TSAN CHANG UNDER 37 C.F.R. § 1.131

I, Wen-Tsan Chang, hereby declare as follows:

1. I am a co-inventor of the subject matter described and claimed in the above-captioned application, which relates to an RNA molecule for inhibiting expression of a gene of a virus.

2. I have reviewed the office action, dated April 18, 2007, issued in this application. In this office action, claims 27-29 and 32-34 remain rejected under 35 U.S.C. § 102(e) as being anticipated by Morrissey *et al.*, US Patent Application Publication 2003/0206887 ("Morrissey"). Morrissey was filed on September 16, 2002.

3. On a date prior to September 16, 2002, I or another co-inventor, carried out experiments to examine inhibition of HBsAg expression by a vector encoding HBsAg-3 (SEQ ID NO: 3). A copy of the results is attached hereto as "Exhibit A" with the report date, which is also prior to September 16, 2002, blocked off.

The experiments were carried out in the manner described in the Example section of the instant application. Briefly, Huh7 cells were co-transfected with:

- (i) 0.5 µg of p(3A)Sag ("Sag 0.5") and 1.5 µg of pSUPER ("pSUPER 1.5"),
- (ii) 1.0 µg of p(3A)Sag ("Sag 1.0") and 1.0 µg of pSUPER ("pSUPER 1.0"),
- (iii) 0.5 µg of p(3A)Sag and 1.5 µg of the vector encoding HBsAg-3 ("HBVsAg-3 1.5"), or
- (iv) 1.0 µg of p(3A)Sag and 1.0 µg of the vector encoding HBsAg-3 ("HBVsAg-3 1.0").

The expression level of HBsAg was examined by enzyme-linked immunosorbent assay (ELISA). Each assay was carried out in triplicate. It was found that the HBsAg levels ("Mean") in the cells transfected with the vector encoding HBsAg-3 ("UNK 19" to "UNK 24") were lower than

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those in the cells transfected with the control backbone vector pSUPER ("UNK1" to "UNK6") by more than 90%.

4. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

Date: July 16, 2007

Wen-Tsan Chang
Wen-Tsan Chang
Associate Professor
Department of Biochemistry and Molecular
Biology, National Cheng Kung University
Medical collage
1, University Road, Tainan 701, Taiwan, ROC